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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,341	07/21/2000	Keiji Enpuku	017348/0361	3693

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/26/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/621,341

Applicant(s)

ENPUKU, KEIJI

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 02, 2003 has been entered.

Claim Status

Claims 1-4, 12-15 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 12-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4)

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the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention: - the instant invention is directed to a method for immunoassay using a magnetic material label and a SQUID device comprising labeling an analyte with a magnetic material label; subjecting the magnetic material label to a magnetic field; using a SQUID to detect a variation of strength of a magnetic field which is at a right angle to the magnetic field which magnetizes the magnetic material label.

The state of the art: - the prior art teaches that the analyte is labeled with a magnetic particle coated with a binder that binds to the analyte. Then the mixture is separated by a magnetic field. After that, a fluorescent or color label is added and detection occurs.

The predictability or lack thereof in the art: - in view of the teachings in the prior art that show or suggests that the magnetic material label must have a binder that binds to the analyte, the predictability of using the magnetic material label without a binder to the analyte is low.

The amount of direction or guidance present: - the instant specification, example 3, discloses that antigen/analyte is fixed by a first antibody/capture antibody to a support. Then a second antibody binds to selectively to the antigen. Furthermore, a third antibody labeled with a magnetic material binds to the second antibody. A magnetic field is applied to the mixture. Then, the SQUID detects the magnetic material.

The presence or absence of working examples:- there is no examples in the specification that shows the analyte alone would bind to the magnetic material label without a binder either attached to the magnetic material label or bound to the analyte before contacting the magnetic material label. Furthermore, the specification also do not provide working examples of how the bound and unbound magnetic material labels are separated and how the various strength of magnetic field correlates to the presence/absence or concentration of the analyte.

The quantity of experimentation necessary: - it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed.

The relative skill of those in the art: The level of skill in the art is high.

The breadth of the claims:- the claimed method is directed to using a magnetic label to label analyte and subject said mixture to a magnetic field. Then the SQUID detects the various strength of a magnetic field that is perpendicular to the magnetic field, which magnetizes the magnetic label and the analyte.

The claims of the present invention recite that the analyte is labeled with a magnetic material label. Then the magnetic material label is subjected to a magnetic field without separation of the bound and unbound. In this case, the magnetic field would attract the bound and the unbound. Then how are the bound analytes distinguished from the unbound? The SQUID detects a magnetic field, which is perpendicular to the first magnetic field. However, the specification fails to correlates such detection using the SQUID with the presence/absence/concentration of the analytes being detected in the immunoassay. Without a critical element such as a second label, i.e. a fluorescent or

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color particle, one of ordinary skills in the art would not able to detect the analytes using just the magnetic fields. Furthermore, while the specification teaches that the magnetic material label is bound to a binder, second antibody, which binds the analyte, the claims fail to recite such critical element, which is essential to the practice of the invention.

Thus, these claims are not enabled by the disclosure. See *In re Mayhew*, 527

F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Weitschies et al. (US 6,027,946).

Weitschies teaches a process for quantitative detection of analytes in liquid and solid phases by labeling an analyte of interest with colloidal ferromagnetic substances or magnetic labels (see col. 2, lines 60-65); magnetizing the magnetic labeled analytes;

measuring analytes by using a SQUID (superconducting quantum interference device).(see col. 3, line 60-col. 4, line 2; col. 4, lines 18-36). A static magnetic field is a magnetic field that does not change and produced by a natural or synthetic magnet. Thus, the magnetic field of Weitchies applies to the static magnetic field of the present invention. When a magnetic field is applied, the magnet is pulling the magnetic material. Magnetic fields have parallel lines of force so the analyte that is labeled with magnetic material will move parallel to the magnetic field.

Response to Arguments

Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive.

The rejection under 112, 1st paragraph has not been resolved by the amendment made to the independent claims 1 and 12. The claims fail to recite a separation step or at least a correlation between the SQUID device with the presence or absence or concentration of the analytes being detected in the immunoassay.

Applicant submits that the references fails to teach that the magnetic label which is magnetized by the magnetic field is detected by the SQUID which detects a variation of the strength of a magnetic field which is at a right angle to the magnetic field which magnetizes the magnetic material label. Applicants also submit that Weitschies reference describes a method in which the magnetic field for magnetization is offloaded while detecting with the SQUID; whereas in the applicant's invention, the variation of the magnetic field is in the perpendicular direction is detected while the analyte is in the magnetic field, which is utilized to magnetize the label.

Weitschies teaches in figure 1 that the sample is magnetized by the magnetizing coil and above that is the SQUID, which detects the magnetic field. In figure 1, the magnetizing coils pull the magnetic labels to the sides that create horizontal lines of force. The SQUID that is positioned above the sample substrate detects magnetic field, which is perpendicular to the horizontal lines of force created by the magnetizing coils on the side of the sample substrate. With the above teachings, Weitschies satisfies the requirement of the present claims because the reference teaches detecting magnetizable material labeled analyte by the SQUID which detects a variation of a strength of the magnetic field which is at a right angle to the magnetic field which magnetizes the magnetic field. Moreover, the present claims fail to exclude that the magnetic field is offloaded while detecting with SQUID because they contain an opening language.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
August 22, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641